lecting meaningful and responsive quality of life instruments for use in clinical trials and other evaluative studies.

Health outcomes and quality of life assessment is becoming increasingly important in the evaluation of pharmaceutical products, in terms of labeling claims and product promotion as well as in terms of formulary decisions. Each of these uses requires an assessment strategy that provides information relevant for decision-making. What are the components of a successful strategy? How is a given strategy evaluated to select the best for the given evaluative study? This workshop will address these questions and introduce an analytic framework that participants can apply in their daily experience.

SESSION 3

WPE7

SCHIZOPHRENIA: HELPING THE DECISION-MAKER TO UNDERSTAND THE IMPACTS OF ATYPICAL ANTIPSYCHOTICS

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WORKSHOP OBJECTIVE: The purpose of this workshop is to demonstrate, using a schizophrenia case study, how prevalence-based drug value information can be presented in a format that is understandable and useful for decision-makers.
PARTICIPANTS WHO WOULD BENEFIT: Those who want to learn a process that will increase the likelihood that prevalence-based drug value analyses are used by decision-makers.

Although many drug value analyses have been completed in recent years, it is not clear to what extent these analyses have been used to inform decisions. In a recent paper, Mauskopf (VH 1998) has suggested that prevalence-based annual estimates of population and cost outcomes would be of value to decision-makers. In this workshop, we will take the participants through a series of activities designed to ensure that decision-makers can understand and use the results of prevalence-based drug value analyses. We will illustrate these activities using a project that we recently completed for schizophrenia. In this project, we developed an interactive computer model to estimate the impacts of the atypical anti-psychotics on patient and family outcomes and healthcare costs for a population of schizophrenia patients. The project included three main activities: 1) develop a preliminary model; 2) present the model to decision-makes to determine its value to them; and 3) revise the model based on decision-maker comments and create an interactive computer version of the model. We will show the workshop participants how we presented our model to the decision-makers. We will summarize the decision-makers responses to the presentation. We will then lead the workshop participants in a discussion about the range of possible responses to these comments and the trade-offs between 1) keeping a model well grounded in published literature; and 2) extrapolating information to address outcomes that are important to decision-makers, but not well researched. We will conclude the workshop by describing how we modified the preliminary model in response to the decision-makers' comments and by showing the final interactive computer model.

WPE8

DESIGNING NATURALISTIC OUTCOMES TRIALS THAT ARE APPLICABLE TO THE "REAL WORLD" OF CLINICAL PRACTICE

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WORKSHOP OBJECTIVE: To highlight design features that characterize state-of-the-art studies evaluating outcomes of competing pharmacotherapies, balancing the need to maintain internal validity with the goal of providing information that can be applied to the "real world" of clinical practices.
PARTICIPANTS WHO WOULD BENEFIT: 1) Outcomes researchers, statisticians, health economists, and others who wish to expand beyond the traditional clinical trial design; and 2) clinicians, healthcare organizations, and others who wish to learn more about how to make informed decisions based on comparative cost and effectiveness claims.

Various methodological issues are critical in the design of naturalistic outcomes trials. These include how narrowly (or broadly) to define the patient population, whether or not to "blind" the study, how much physician discretion to allow in treating patients, and how to obtain and analyze data on patients who switch from their originally-assigned medication (or on patients who discontinue medication). Additionally, the definition of comparator(s) and the appropriate time horizon of the study are important. These and other issues will be discussed and illustrated through examples of two randomized naturalistic trials designed by the workshop leaders and colleagues. One study is designed to answer the question of whether using an atypical antipsychotic agent as first-line therapy is more effective and less costly than requiring a patient to first fail on conventional medications. The other study is designed to determine how three different selective serotonin reuptake inhibitors compare in terms of various outcome measures including patient adherence, quality of life, and resource utilization. The authors will discuss the decisions made in designing these trials and the implications of these decisions for data analysis and interpretation of findings.

WPE10

GUIDELINES FOR THE ECONOMIC EVALUATION OF PHARMACEUTICALS: CURRENT USE AND EMERGING TRENDS

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WORKSHOP OBJECTIVE: The purpose of this workshop will be to review guidelines in current use and under development to determine similarities, emerging trends and the implications for the use and development of guidelines in the future.
PARTICIPANTS WHO WOULD BENEFIT: Those who want to develop an understanding of the guidelines process and the means of establishing appropriate study design criteria to apply in international pharmacoeconomic studies in order to meet the requirements of as many guidelines as possible.

Guidelines for the economic evaluation of pharmaceuticals are being developed around the world by academia, industry, government, payers and external consultants. These guidelines can be categorized according to their main purpose: methods guidelines; guidelines for formulary submissions; principles of conduct; and substantiation of evidence for promotional claims. Review of the guidelines reveals a number of common themes which will allow some comparison of studies across countries. Differences outside these common themes may be attributable to particular differences in the settings in which individual guidelines are applicable. However, what is most noticeable is the trends emerging from what appears to be a flourishing field of guidelines development. Methodological trends are evident in study design (with greater acceptance of modelling studies), valuation of health outcomes and productivity changes (indirect costs). In addition, the formal requirement for economic evaluation of pharmaceuticals is being extended into more countries and we can expect to see pharmacoeconomic guidelines being increasingly used. If this encourages cost-effective prescribing then the ultimate impact will be in providing benefit to patients.

WTG2

UPDATE ON THE SCRIPT PROJECT

Westrick E
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WORKSHOP OBJECTIVE: The objective of this workshop is to update participants on the progress of the SCRIPT project.
PARTICIPANTS WHO WOULD BENEFIT: Stakeholders in medication use quality would benefit by participating in this workshop.

Background for the SCRIPT project was presented at last year's meeting of ISPOR in Philadelphia. Since that time, there has been significant progress. The SCRIPT project is the first concerted effort of the Coalition for Quality in Medication Use. The purpose of the project is to create a method for consensus-based quality indicator development and a compendium of core indicators measuring quality in medication use that will be recommended for implementation by coalition members. The Coalition for Quality in Medication Use currently includes about 50 national organizations. The SCRIPT project is funded by HCFA, and staffed by JCAHO. Daily management is provided by a Steering Committee composed of representatives from AAHP, AHCPR, AHQA, AMA, APhA, HCFA, JCAHO, NCQA, and two science advisors. The coalition met for the first time in July 1998. A Call for Measures has gone out and existing compendia of measures have been collected. Criteria for evaluating measures are in development and a technical expert panel is being formed to evaluate the measures in a cluster of clinical conditions with high disease burden and significant quality issues in medication use. Clinical conditions, medication use issues, and some of the considered measures will be identified at this workshop. Additional progress in this area will be shared in the workshop as well as preliminary plans to test candidate measures.

WTG5

EVALUATION OF FORMULARY DECISIONS: PROJECTED IMPACT OF A NEW DRUG ROLLOUT WITHIN THE MANAGED CARE ARENA

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WORKSHOP OBJECTIVE: The purpose of this workshop will be to demonstrate the nature of decision-making tools employed within the managed care industry to evaluate pharmacy-related issues. This workshop will use an economic model to demonstrate the type of logic used by MCOs to project pharmacy costs and to evaluate the impact of formulary changes. Participants will learn how to utilize pharmacy and medical administrative claims data to assess the potential increase in pharmacy costs associated with the introduction of new drugs and/or treatments.
PARTICIPANTS WHO WOULD BENEFIT: Managed care decision-makers, pharmacy directors, and health economists who are involved in the evaluation of pharmacy costs and business issues related to formulary changes.

Rising pharmaceutical expenditures in recent years have led to increased scrutiny of this benefit among healthcare insurers in the United States. Managed care organizations (MCOs) are increasingly questioning available options with regard to the introduction of new classes of prescription drugs and other new therapies. Economic models are an important vehicle that may be utilized by decision-makers to better understand the financial implications of formulary changes. We will discuss a model recently developed to simulate the impact of prescription Cox-2 inhibitor medications on pharmacy costs of a managed care health plan. This session will explain the assumptions made, data used, and processes employed in the development of this economic model.

WDM3

APPLYING PRACTICAL APPLICATIONS OF PHARMACOECONOMICS AND OUTCOMES DATA IN THE COMMUNITY HEALTHCARE FACILITY

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